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**PATENT APPLICATION TRANSMITTAL LETTER
(SMALL ENTITY)**

Docket No.
F-146A

TO THE ASSISTANT COMMISSIONER FOR PATENTS

Transmitted herewith for filing under 35 U.S.C. 111 and 37 CFR 1.53 is the patent application of

James D. Ralph and Steven Tatar

For: A Polyaxial Pedicle Screw Having A Threaded And Tapered Compression Locking Mechanism

Enclosed are:

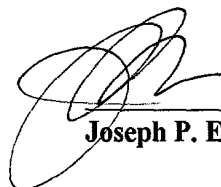
- ☒ Certificate of Mailing with Express Mailing Label: *EI31927798 US*
- ☒ 9 informal sheets of drawings
- ☒ signed Declaration and Power of Attorney
- ☒ signed Verified Statement to Establish Small Entity Status Under 37 CFR 1.9 and 1.27
- ☒ Assignment and Recordation cover sheet

Claims as Filed

For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	11	20	0 X	\$11.00	= \$0.00
Indep. Claims	2	3	0 X	\$40.00	= \$0.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					= \$0.00
					Basic Fee \$385.00
					Total Filing Fee \$385.00

- ☐ A check in the amount of _____ to cover the filing fee is enclosed.
- ☒ The Commissioner is hereby authorized to charge and credit Deposit Account No. 06-0245 as described below. A duplicate copy of this sheet is enclosed.
 - ☒ Charge the amount of \$385.00 as filing fee.
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 - ☒ Charge any additional filing fees required under 37 CFR 1.16 and 1.17.
 - ☐ Charge the issue fee set in 37 CFR 1.18 at the mailing of the Notice of Allowance pursuant to 37 CFR 1.311(b).

Dated: January 2, 1998


Joseph P. Errico, Esq.

CERTIFICATE OF MAILING (UNDER 37 CFR 1.08 AND 1.10)

Docket No.
F-146A

TO THE ASSISTANT COMMISSIONER FOR PATENTS

I hereby certify that this correspondence is being deposited on January 2, 1998 with the United States Postal Service's "Express Mail Post Office to Addressee" service and is addressed to Assistant Commissioner for Patents, Box New Patent Applications, Washington, D.C. 20231.

documents included:

- ☒ Specification and claims
- ☒ 9 informal sheets of drawings
- ☒ signed Declaration and Power of Attorney
- ☒ signed Verified Statement to Establish Small Entity Status Under 37 CFR 1.9 and 1.27
- ☒ Assignment and Recordation cover sheet

signed: _____

Joseph P. Errico, Esq.
Reg. No. 38,131

dated: _____

1/2/98
January 2, 1998

APPLICATION FOR LETTERS PATENT OF THE UNITED STATES

OF AMERICA

OF

JAMES D. RALPH

AND

STEVEN TATAR

FOR

A POLYAXIAL PEDICLE SCREW HAVING A THREADED
AND TAPERED COMPRESSION LOCKING MECHANISM

A POLYAXIAL PEDICLE SCREW HAVING A THREADED AND TAPERED COMPRESSION LOCKING MECHANISM

Cross-reference to Prior Application

This application is a continuation-in-part of prior application U.S.S.N. 08/663,383, entitled "A Polyaxial Pedicle Screw", filed June 16, 1996, and which, in turn, was a continuation-in-part of now issued U.S. Patent No. 5,520,690, entitled "An Anterior Spinal Polyaxial Locking Screw Plate Assembly".

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to a polyaxial screw and coupling apparatus for use with orthopedic fixation systems. More particularly, the present invention relates to a screw for insertion into spinal bone, and a coupling element polyaxially mounted thereto, via a two-piece interlocking coupling element having a socket portion and a threaded compression member, for coupling the screw to an orthopedic implantation structure, such as a rod, therein enhancing the efficacy of the implant assembly by providing freedom of angulation among the rod, screw and coupling element.

2. Description of the Prior Art

The bones and connective tissue of an adult human spinal column consists of more than 20 discrete bones coupled sequentially to one another by a tri-joint complex which consist of an anterior disc and the two posterior facet joints, the anterior discs of adjacent bones being cushioned by cartilage spacers referred to as intervertebral discs. These more than 20 bones are anatomically

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categorized as being members of one of four classifications: cervical, thoracic, lumbar, or sacral. The cervical portion of the spine, which comprises the top of the spine, up to the base of the skull, includes the first 7 vertebrae. The intermediate 12 bones are the thoracic vertebrae, and connect to the lower spine comprising the 5 lumbar vertebrae. The base of the spine is the sacral bones (including the coccyx). The component bones of the cervical spine are generally smaller than those of the thoracic and lumbar spine. For the purposes of this disclosure, however, the word spine shall refer only to the cervical region.

Referring now to Figures 1, 2, and 3, top, side, and posterior views of a vertebral body, a pair of adjacent vertebral bodies, and a sequence of vertebral bodies are shown, respectively. The spinal cord is housed in the central canal 10, protected from the posterior side by a shell of bone called the lamina 12. The lamina 12 includes a rearwardly and downwardly extending portion called the spinous process 16, and laterally extending structures which are referred to as the transverse processes 14. The anterior portion of the spine comprises a set of generally cylindrically shaped bones which are stacked one on top of the other. These portions of the vertebrae are referred to as the vertebral bodies 20, and are each separated from the other by the intervertebral discs 22. The pedicles 24 comprise bone bridges which couple the anterior vertebral body 20 to the corresponding lamina 12.

The spinal column of bones is highly complex in that it includes over twenty bones coupled to one another, housing and protecting critical elements of the nervous system having innumerable peripheral nerves and circulatory bodies in close proximity. In spite of these complexities, the spine is a highly flexible structure, capable of a high degree of curvature and twist in nearly every direction. Genetic or developmental irregularities, trauma, chronic stress, tumors, and disease, however, can result in spinal pathologies which either limit this range of motion, or which

threaten the critical elements of the nervous system housed within the spinal column. A variety of systems have been disclosed in the art which achieve this immobilization by implanting artificial assemblies in or on the spinal column. These assemblies may be classified as anterior, posterior, or lateral implants. As the classifications suggest, lateral and anterior assemblies are coupled to the anterior portion of the spine, which is the sequence of vertebral bodies. Posterior implants generally comprise pairs of rods, which are aligned along the axis which the bones are to be disposed, and which are then attached to the spinal column by either hooks which couple to the lamina or attach to the transverse processes, or by screws which are inserted through the pedicles.

"Rod assemblies" generally comprise a plurality of such screws which are implanted through the posterior lateral surfaces of the laminae, through the pedicles, and into their respective vertebral bodies. The screws are provided with upper portions which comprise coupling elements, for receiving and securing an elongate rod therethrough. The rod extends along the axis of the spine, coupling to the plurality of screws via their coupling elements. The rigidity of the rod may be utilized to align the spine in conformance with a more desired shape.

It has been identified, however, that a considerable difficulty is associated with inserting screws along a misaligned curvature and simultaneously exactly positioning the coupling elements such that the rod receiving portions thereof are aligned so that the rod can be passed therethrough without distorting the screws. Attempts at achieving proper alignment with fixed screws is understood to require increased operating time, which is known to enhance many complications associated with surgery. Often surgical efforts with such fixed axes devices cannot be achieved, thereby rendering such instrumentation attempts entirely unsuccessful.

The art contains a variety of attempts at providing instrumentation which permit a

limited freedom with respect to angulation of the screw and the coupling element. These teachings, however, are generally complex, inadequately reliable, and lack long-term durability. These considerable drawbacks associated with prior art systems also include difficulty properly positioned the rod and coupling elements, and the tedious manipulation of the many small parts in the operative environment.

It is, therefore, the principal object of the present invention to provide a pedicle screw and coupling element assembly which provides a polyaxial freedom of implantation angulation with respect to rod reception.

In addition, it is an object of the present invention to provide such an assembly which comprises a reduced number of elements, and which correspondingly provides for expeditious implantation.

Accordingly it is also an object of the present invention to provide an assembly which is reliable, durable, and provides long term fixation support.

Other objects of the present invention not explicitly stated will be set forth and will be more clearly understood in conjunction with the descriptions of the preferred embodiments disclosed hereafter.

SUMMARY OF THE INVENTION

The preceding objects of the invention are achieved by the present invention which is a polyaxial locking screw and coupling element for use with rod stabilization and immobilization systems in the spine. More particularly, the polyaxial screw and coupling element assembly of the present invention comprises a bone screw having a head which is curvate in shape, for example semi-spherical, and a two-piece interlocking coupling element mounted thereto. This combination is

mounted inside the bottom of an internal channel of a cylindrical body member.

More specifically, with respect to the cylindrical body member, the tubular body comprises a rod receiving channel formed in the upper portion thereof, with a threading formed on the remaining upper elements so that a rod securing nut and/or set screw may be threaded thereon once a rod has been placed in the channel. The body further includes an axial bore which includes extends from the rod receiving channel through to the bottom of the cylinder. The portion of the axial bore which is below the channel forms a receiving chamber, the upper portion thereof having a constant diameter, and the lower portion of the chamber being inwardly tapered. The inner surface of the upper portion of the chamber and/or the inner surface of the portion of the axial bore which is above the chamber may further include a threading.

The two-piece interlocking coupling element comprises a socket portion and a cap portion. The socket portion is designed with an interior semi-spherical volume, so that it may receive the semi-spherical head of a corresponding bone screw. The interior volume of the socket portion is open at both axial ends thereof. The exterior surface of the socket portion, at the bottom thereof, includes a first set of slots which extend upwardly from the opening so that the interior semi-spherical volume may be expanded or contracted by the application of a radial force. In addition, the exterior surface at the bottom is tapered so that it is narrower at the bottom than at a midpoint. This taper is designed to mate with and nest in the tapered lower portion of the socket portion of the axial bore of the body member.

The upper exterior surface of the socket portion comprises a second set of slots, directed axially along the element to the midpoint, such that the upper opening of the socket element may expand and contract in accordance with the application of a radial force thereon. The exterior

surface of this upper section of the socket portion is not tapered and is narrower than the widest taper position of the bottom of the socket portion. The upper section, however, does further include an outwardly extending annular lip at the uppermost axial position. This upper section is designed to be inserted into, and joined with, the cap portion of the coupling element.

5 The cap portion has a generally cylindrical shape, having an open bottom. The open bottom is inwardly tapered, forming an inwardly extending annular lip, so that as the upper end of the socket portion is inserted, its upper slots are narrowed. Once axially inserted beyond this taper, the upper section of the socket portion expands outward over the inwardly extending annular lip. The inwardly extending annular lip engages the outwardly extending lip of the socket portion so as to prevent disengagement of the two pieces. The socket portion is then permitted to slide into the cap portion, until the larger diameter of the tapered lower portion of the socket contacts the entrance of the cap portion.

10 The exterior surface of the cap portion may be threaded, so that it may engage a threading of the upper portion of the socket portion and/or the inner surface of the axial bore which is above the socket portion. In addition, the top of the cap includes an opening so that a screw driving tool may directly engage the top of the screw.

15 The assembly of the entire device begins with the joining of the socket portion to the cap portion of the two-piece interlocking coupling element. This is achieved by the slideable interlocking mating of the two elements. Next, the semi-spherical head of the screw is inserted into the socket portion through the lower expandable opening in the taper portion. Once these parts have
20 been assembled the screw and coupling element should be polyaxially rotateable relative to one another. The screw and coupling element are then inserted through the axial bore of the body (which

may require the threading the cap portion of the coupling element along the threading on the inner surface of the axial bore and/or the threading of the cap along the threading of the upper portion of the chamber) until the socket portion nests in the tapered lower portion of the axial bore. If the upper portion of the chamber includes a threading it should not extend beyond the point of the initial nesting of the coupling element in the chamber. This is important because the cap portion must be able to move relative to the socket portion.

In this initial position, the top of the cap portion should rest above the bottom of the rod receiving channel so that a rod, when placed therein, seats directly onto the top of the cap. This direct contact provides the downward force necessary to compress the coupling element into the chamber so that the socket portion is compressed in the tapered portion and locks to the head of the screw.

In a preferred variation of this embodiment, the interior surface of the cap portion includes a slight narrowing taper so that as the cap is compressed downward by the rod, the upper slots of the socket portion are also narrowed, further increasing the crush locking effect on the head of the screw.

The implantation of this screw by a surgeon may proceed first by the assembly of the screw into its initial state. The shaft of the screw is then driven into the vertebral bone at the desired angulation. A rod is then introduced into the rod receiving channel, and the body is angulated into the most ideal position for receiving the rod. A nut and/or set screw is then used to secure the rod in the channel, and simultaneously to provide a sufficient downward translational force to cause the socket portion to be driven into the tapered portion of the chamber in the axial bore, and further to cause the cap portion to drive downwardly also (this further compression locking the screw head in

the embodiment wherein the sliding of the cap portion toward the socket portion provides an additional compression on the top of the socket portion and therefore onto the head of the screw).

In a preferred variation, the locking nut comprises a cap nut which has a central post which is designed to provide additional structural support to the inner walls of the element at the top thereof, as well as providing a central seating pressure point for locking the rod in the channel. In either variation, the locking nut seats against the rod and prevents it from moving translationally, axially and rotationally.

Multiple screw assemblies are generally necessary to complete the full array of anchoring sites for the rod immobilization system, however, the screw assembly of the present invention is designed to be compatible with alternative rod systems so that, where necessary, the present invention may be employed to rectify the failures of other systems when the surgery may have already begun.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a top view of a human vertebra, which is representative of the type for which the present invention is useful for coupling thereto a rod apparatus;

Figure 2 is a side view of a pair of adjacent vertebrae of the type shown in Figure 1;

Figure 3 is a posterior view of a sequence of vertebrae of the type shown in Figures 1 and 2;

Figure 4 is a side view of a screw having a curvate head which is an aspect of the present invention;

Figure 5 is a side view of a two-piece interlocking coupling element of present

invention;

Figure 6 is a side view of a two-piece interlocking coupling element of present invention mounted around the head of a screw of the type shown in Figure 4;

Figure 7 is a side cross-sectional view of a cylindrical body having a chamber for receiving the two-piece interlocking coupling element and the screw of the present invention;

Figure 8 is a side cross-sectional view of a top locking nut which is an aspect of the present invention;

Figure 9 is a side cross-sectional view of an embodiment of the present invention in its fully assembled disposition having a rod securely locked therein; and

Figure 10 is a side view of an alternative embodiment of the present invention in its fully assembled disposition having a rod securely locked therein.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

While the present invention will be described more fully hereinafter with reference to the accompanying drawings, in which particular embodiments and methods of implantation are shown, it is to be understood at the outset that persons skilled in the art may modify the invention herein described while achieving the functions and results of this invention. Accordingly, the descriptions which follow are to be understood as illustrative and exemplary of specific structures, aspects and features within the broad scope of the present invention and not as limiting of such broad scope.

Referring now to Figure 4, a side view of the screw portion of the present invention, comprising a curvate head, is shown. The screw 120 comprises a head portion 122, a neck 124, and

variety of angles while still being securely joined to the locking collar (as set forth more fully with respect to Figures 5, 8-9, and 11).

Referring now to Figure 5, the two elements which form the two-piece interlocking coupling element of the present invention are shown in a side cross-section view. Phantom lines show the interior structure of the elements along the diametrical cross section. With specific reference to the socket portion 132, the coupling element comprises a roughly cylindrical shape having an interior volume 134 in which the semi-spherical head 122 of the screw 120 is disposed. The interior volume 134 is open at the top 136 of the socket portion 132 and at the bottom thereof 138. The lower section 131 of the socket portion 132 comprises a set of slots 133 which extend vertically from the bottom 138 of the socket portion 132 to a position above the maximum diameter of the semi-spherical interior volume 134. These slots 133 permit the interior volume to expand and contract in accordance with the application of a radial force thereon. The external surface 135 of the lower section 131 of the socket portion 132 is tapered such that the narrowest part of the lower section 131 is at the bottom 138.

The upper section 139 of the socket portion 132 has a generally constant diameter, which is less than the diameter at the uppermost position 137 of the taper of the lower section 131. A second set of vertical slots 141 are provided in this upper section 139 so that it may also expand and contract in accordance with radial forces applied thereto. In addition, the uppermost end of this upper section 139 comprises an outwardly extending annular lip 140.

The cap portion 142 of the coupling element comprises an opening 143 in the bottom thereof, having an inwardly tapered entrance surface conformation 144. As the upper section 139 of the socket portion 132 is inserted into the opening 143 in the cap portion 142, the taper 144 of the

opening 143 provides an inwardly directed force which causes the upper section 139 to contract (causes the slots 141 to narrow). This tapered entrance 144 opens to form an annular lip 145 which is useful for engaging and retaining the annular lip 140 of the upper section 139 of the socket portion 132. The interior surface 146 of the cap portion has a constant diameter, therein permitting the inserted upper section 139 of the socket portion 132 to slide and rotate relative to the cap portion 142.

The exterior surface of the cap portion 142 comprises a threading 147 which is designed to engage threadings 211 disposed in the axial bore of the rod receiving body member (see Figure 7). In addition, the cap portion 142 comprises an axial hole 148 through which a surgeon may insert a screw driving tool to access the head of the screw which is positioned in the interior volume 134 of the socket portion 132.

More particularly, with respect to the disposition of the head 122 of the screw 120 in the socket portion 132, and with reference to Figure 6, a partially assembled screw 120 and coupling element is shown in a side cross-section view. The top 136 of the socket portion 132 is inserted into the opening in the cap portion 142 until the annular lip 140 of the socket 132 seats into the cap 142. The screw 120 is loosely held within the socket 132, which is, in turn, loosely retained within the cap 142.

Referring now to Figure 7, the rod receiving body member 200 of the present invention is shown in a side view, wherein critical features of the interior of the element are shown in phantom. The body member 200, which comprises a generally cylindrical tubular body having an axial bore 201 extending therethrough, may be conceptually separated into a chamber portion 202 at the bottom of the axial bore 201, and an upper rod receiving channel portion 204, each of which

shall be described more fully hereinbelow.

The upper rod receiving channel portion 204 of the body 200 includes a channel 206 formed therein, having rounded bottom surfaces 207. The channel 206, in turn, divides the walls of the cylindrical body of the upper portion 204 into a pair of upwardly extending members 214a, 214b.

5 As shown in the embodiment illustrated in Figure 7, the vertical distance from the top 208 of the channel to the curvate bottom 207 thereof, is larger than the diameter of the rod which is to be provided therein. This distance is necessarily larger than the diameter of the rod (see Figures 9 and 10) so that the rod may be fully nested in the channel 206. In addition, the depth of the bottom curvate surface 207 of the channel is such that the cap portion 142 of the two-piece interlocking coupling element initially seats above the curvate bottom 207 of the body 200.

The upwardly extending members 214a, 214b further have, disposed thereon, a threading 216 (which may be provided on the inner and/or outer circumferential surfaces, but which is shown in Figures 7, 9 and 10 as being on the inner circumferential surface). This threading 216 is ideally suited for receiving a top locking nut (see Figure 8).

10 Referring now to the lower portion of the body, the chamber portion 202 can further be subdivided into a lower chamber portion 203 which includes an inwardly tapered surface, and an upper chamber portion 205 which has a constant diameter. The inwardly tapered portion 203 defines a nesting volume into which the socket portion 132 may nest. Prior to its being fully driven into this nesting volume, the socket portion 132 and the screw 120 disposed therein may be angulated relative to one another, and the screw 120 may be angulated relative to the body 200. Once driven fully into the tapered lower chamber portion 203, however, the taper of the axial bore 201 provides the necessary inwardly directed radial force to cause the socket portion 132 to crush lock to the head 122

of the screw 120.

The force which causes the socket portion 132 to be driven downwardly into the tapered lower chamber portion 203 is provided by the cap portion 142. More specifically, as stated above, when the initially assembled screw 120 and coupling element combination 132 and 142 (see Figure 6) is advanced into the bottom of the axial bore 201 of the body 200, and the socket portion 132 nests in the lower chamber portion 203, the top of the cap portion 142 is positioned to receive the rod (see Figures 9 and 10) directly thereon. The locking of the rod in the channel 206 of the body 200 causes the cap portion 142 to be forced downwardly onto the socket portion 132, which in turn drives the socket portion 132 into the tapered lower chamber portion 203 and causes it of compression lock to the head 122 of the screw 120.

Referring now to Figure 8, a top locking nut 185 is shown in side cross-section view. The nut 185 comprises post portion 186 and a flange portion 187, each of which is rotationally free, relative to the other. The post portion 186 includes a threading 188 thereon, for engaging and advancing along a threading 216 on the inner surface of the upwardly extending members 214a, 214b of the upper portion 204 of the body 200. The bottom surface 189 of the flange portion 187 (which does not rotate relative to the body as the post portion 186 is rotationally advanced) is intended to seat against the top surface of the rod 250.

Referring now to Figure 9, in which the fully assembled and body member 200, screw 120, coupling element portions 132 and 142, rod 250 and locking nut 185 are shown in side cross-section views, the implantation of this embodiment is described. First, the screw 120 and the two portions 132 and 142 of the coupling element are assembled into their initial association (see Figure 6). The combination of the screw 120 and the two coupling element portions 132 and 142 are then

advanced down the axial bore 201 of the body 200 until the socket portion 132 nests in the lower chamber 203 and the top of the cap portion 142 seats above the bottom 207 of the channel 206. (This insertion of the subassembly of the screw 120 and coupling element portions 132 and 142 into the axial bore 201 of the body 200 may require the threaded advance of the cap portion 142 along the interior threads 216 of the body.)

The shaft of the screw 120 is then inserted and driven downward into the vertebral bone at the desired angle. Once properly positioned, the body 200 is rotated into the ideal rod receiving position. The rod 250 is then inserted into the channel 206 and the top locking nut 185 is threaded onto the threading 216 and compresses the rod 250 to securely lock it in the channel 206. This downward force of the nut 185 and the rod 250 onto the cap portion 142 causes the cap portion to translate downward thus causing the socket portion 132 to translate downward in the tapered chamber 203 and contract to crush against the head 122 of the screw 120. The assembly is thereby fully locked in position.

Referring to Figure 10, a variation of the above device is shown in a similar cross-section view. In this embodiment, the inner surface 146' of the cap portion 142 is tapered inwardly in the vertical direction so that the downward translation of the cap portion 142 causes the annular lip 140 of the socket portion 132 to be compressed inwardly. This causes the slots 141 of the upper section 139 of the socket portion 132 to narrow. This may be utilized to further clamp the interior volume 134 against the head 122 of the screw 120.

While there has been described and illustrated embodiments of a polyaxial screw and coupling element assembly for use with posterior spinal rod implantation apparatus, it will be apparent to those skilled in the art that variations and modifications are possible without deviating from the

broad spirit and principle of the present invention. The present invention shall, therefore, be limited solely by the scope of the claims appended hereto.

We claim:

1. A polyaxial screw and coupling element assembly for use with orthopedic rod implantation apparatus, comprising:

a screw having a semi-spherical head;

5 a cylindrical body including an axial bore defining a bottom chamber portion at a bottom end thereof and a rod receiving channel at a top end thereof, said bottom chamber portion further defining a tapered lower portion and a constant diameter upper chamber portion, and said top end having a threading thereon;

a two-piece interlocking coupling element including

10 a socket portion having a semi-spherical interior volume for receiving therein the head of said screw, upper and lower sections, and vertical slots formed in said upper and lower sections, at least one of said slots rendering said interior volume expandable and contractable, said lower section having a tapered exterior surface for nesting in said tapered lower chamber portion of said cylindrical body such that forceable advancement of socket portion along the tapered lower chamber portion of the axial bore causes the at least one of said slots to narrow such that the semi-spherical interior volume contract, and

15 a cap portion having an opening in a bottom thereof and an interior chamber extending upwardly therefrom for joining with, and slideably retaining therein, the upper section of said socket portion, said cap portion initially seating with a portion thereof extending into a bottom portion of said rod receiving channel; and

20 a top locking nut, mateable with said threading, for locking a rod in said channel and for applying therethrough a downward force onto said cap portion,

wherein said semi-spherical head portion is rotationally freely mounted within the semi-spherical interior volume of the socket portion prior to said socket portion being forceably advanced into the tapered lower chamber portion of the axial bore, and

whereby downward compression of a rod in said channel portion of said body member, by said top locking nut, onto the cap portion causes the forceable advancement of the socket portion into the tapered lower chamber portion of the axial bore, and locks the screw, coupling element and body relative to one another.

2. The polyaxial screw as set forth in claim 1, wherein said semi-spherical head of said screw further includes a recess formed therein for receiving therein a screwdriving tool such that said screw may be threadably advanced into a vertebral bone.

3. The polyaxial screw as set forth in claim 1, wherein said threading on said top end is on the interior surface of said channel.

4. The polyaxial screw as set forth in claim 3, wherein said cap portion further includes a threading and wherein said cap portion needs to be threadably advanced along the threading to be seated in the bore into its initial position.

5. The assembly as set forth in claim 1, wherein said socket portion further comprises a substantially constant diameter upper section having an outwardly annular extending lip at an extreme end thereof,

wherein said opening in the bottom of the cap portion comprises an inwardly directed annular lip, and

wherein at least one of said vertical slots in the upper section of said socket portion renders the upper section thereof to be expandable and contractable such that the upper section of the socket portion may be forceably inserted into the opening in the bottom of the cap portion so that it may be retained in the interior chamber therein by mutual interference engagement of the inwardly directed annular lip of the cap portion and the outwardly extending annular lip of the socket portion.

6. The assembly as set forth in claim 5, wherein the interior chamber of the cap portion comprises a tapered surface such that advancement thereof into the hole causes an inwardly directed force against the upper section of the socket portion, therein causing the at least one of said vertical slots in the upper section to narrow and causes the upper section to contract and further lock the head of the screw within the interior semi-spherical volume of the socket portion.

7. An orthopaedic implant apparatus having a rod and a plurality of screw and coupling element assemblies, comprising:

at least one screw having a semi-spherical head;

at least one cylindrical body including an axial bore defining a bottom chamber portion at a bottom end thereof and a rod receiving channel at a top end thereof, said bottom chamber portion further defining a tapered lower portion and a constant diameter upper chamber portion, and said top end having a threading thereon;

at least one corresponding two-piece interlocking coupling element including

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a socket portion having a semi-spherical interior volume for receiving therein the head of said corresponding screw, upper and lower sections, and vertical slots formed in said upper and lower sections, at least one of said slots rendering said interior volume expandable and contractable, said lower section having a tapered exterior surface for nesting in said corresponding tapered lower chamber portion of said cylindrical body such that forceable advancement of socket portion along the tapered lower chamber portion of the axial bore causes the at least one of said slots to narrow such that the semi-spherical interior volume contract, and

a cap portion having an opening in a bottom thereof and an interior chamber extending upwardly therefrom for joining with, and slideably retaining therein, the upper section of said socket portion, said cap portion initially seating with a portion thereof extending into a bottom portion of said rod receiving channel; and

at least one corresponding top locking nut, mateable with said threading, for locking a rod in said channel and for applying therethrough a downward force onto said cap portion,

wherein said semi-spherical head portion is rotationally freely mounted within the semi-spherical interior volume of the socket portion prior to said socket portion being forceably advanced into the tapered lower chamber portion of the axial bore, and

whereby downward compression of a rod in said channel portion of said body member, by said top locking nut, onto the cap portion causes the forceable advancement of the socket portion into the tapered lower chamber portion of the axial bore, and locks the screw, coupling element and body relative to one another.

8. The apparatus as set forth in claim 7, wherein said threading on said top end is on the

interior surface of said channel.

9.. The apparatus as set forth in claim 8, wherein said cap portion further includes a threading and wherein said cap portion needs to be threadably advanced along the threading to be seated in the bore into its initial position.

10. The apparatus as set forth in claim 7,

wherein said socket portion further comprises a substantially constant diameter upper section having an outwardly annular extending lip at an extreme end thereof,

wherein said opening in the bottom of the cap portion comprises an inwardly directed annular lip, and

wherein at least one of said vertical slots in the upper section of said socket portion renders the upper section thereof to be expandable and contractable such that the upper section of the socket portion may be forceably inserted into the opening in the bottom of the cap portion so that it may be retained in the interior chamber therein by mutual interference engagement of the inwardly directed annular lip of the cap portion and the outwardly extending annular lip of the socket portion.

11. The apparatus as set forth in claim 10, wherein the interior chamber of the cap portion comprises a tapered surface such that advancement thereof into the hole causes an inwardly directed force against the upper section of the socket portion, therein causing the at least one of said vertical slots in the upper section to narrow and causes the upper section to contract and further lock the head of the screw within the interior semi-spherical volume of the socket portion.

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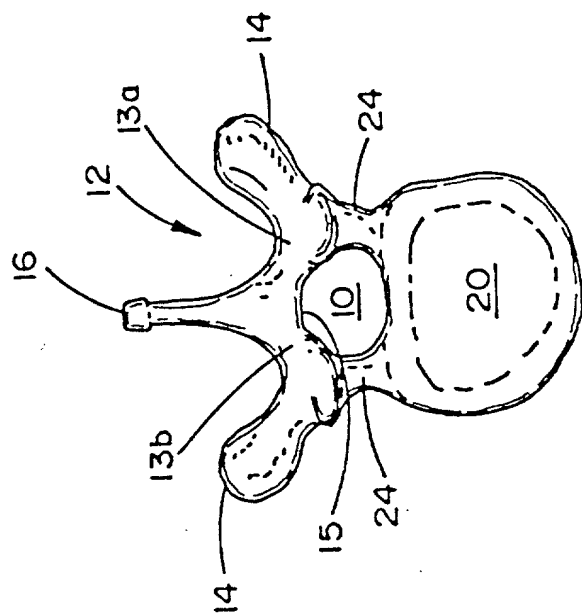


FIG. 1

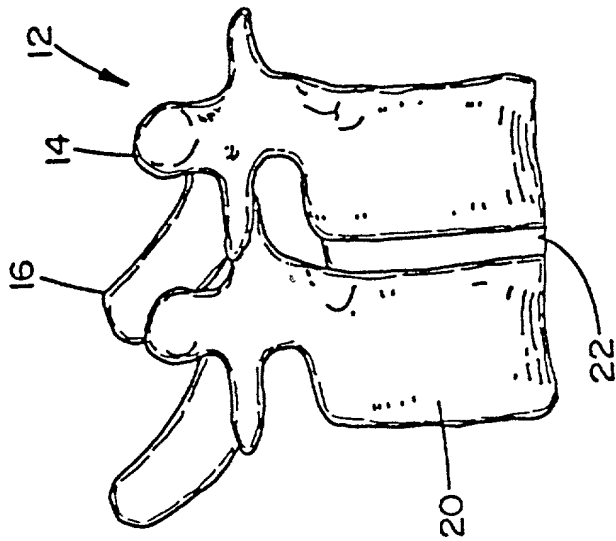


FIG. 2

Figure 1 is a schematic diagram of a vertebral column, showing five vertebrae stacked vertically. Each vertebra consists of a central body (10) and a central canal (12). The vertebral body is labeled 14, and the vertebral canal is labeled 16. The intervertebral disc is labeled 19. The diagram illustrates the arrangement of the vertebral bodies and the central canals, showing how they are connected by the intervertebral discs.

3

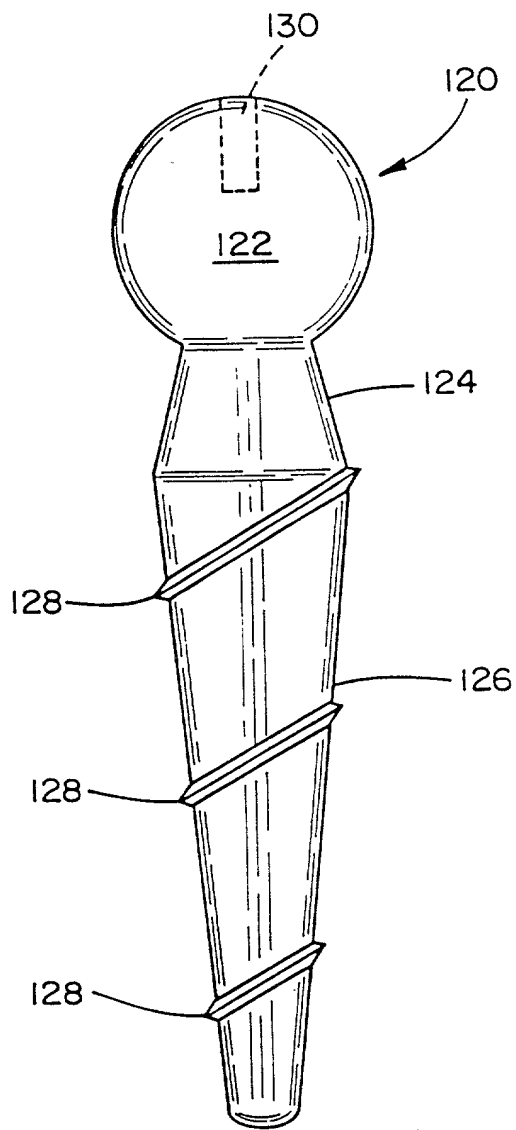
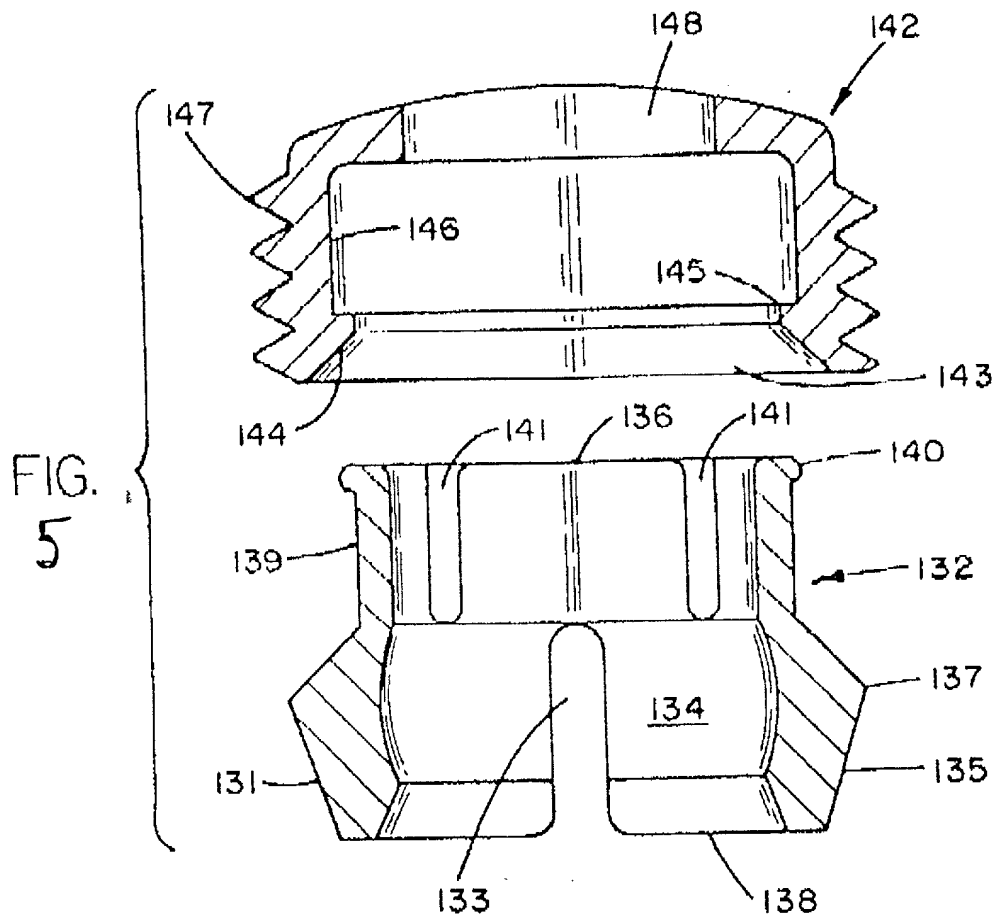


FIG. 4



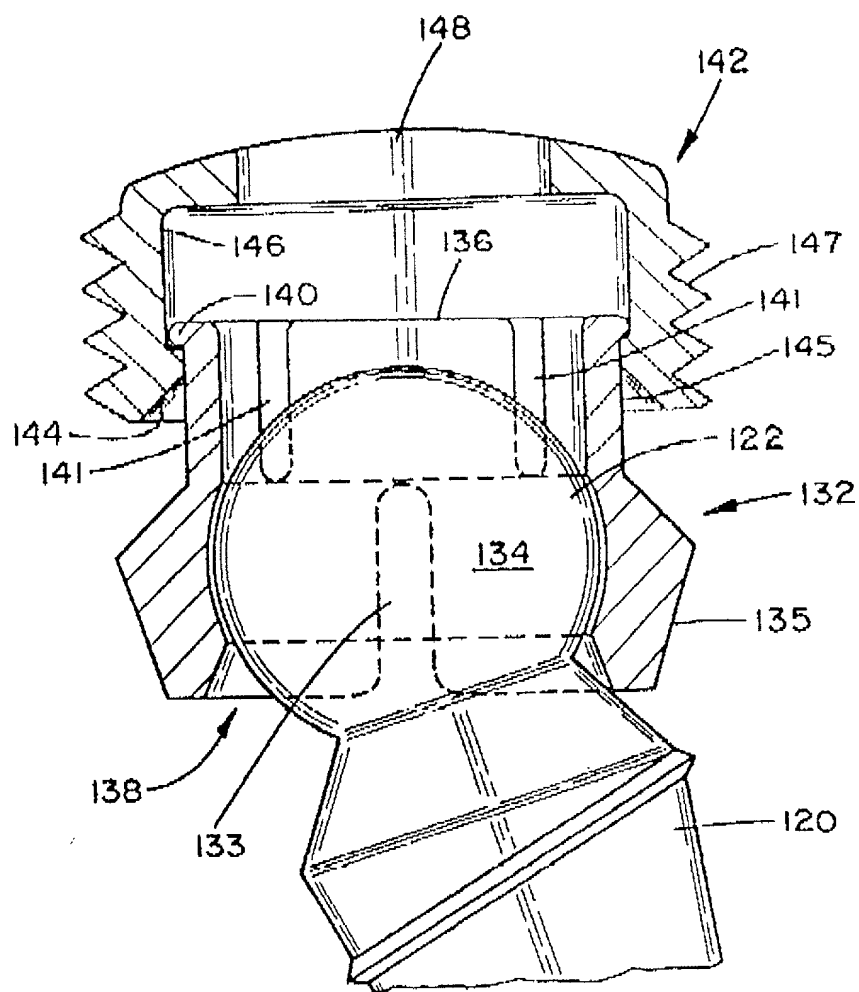


FIG. 5

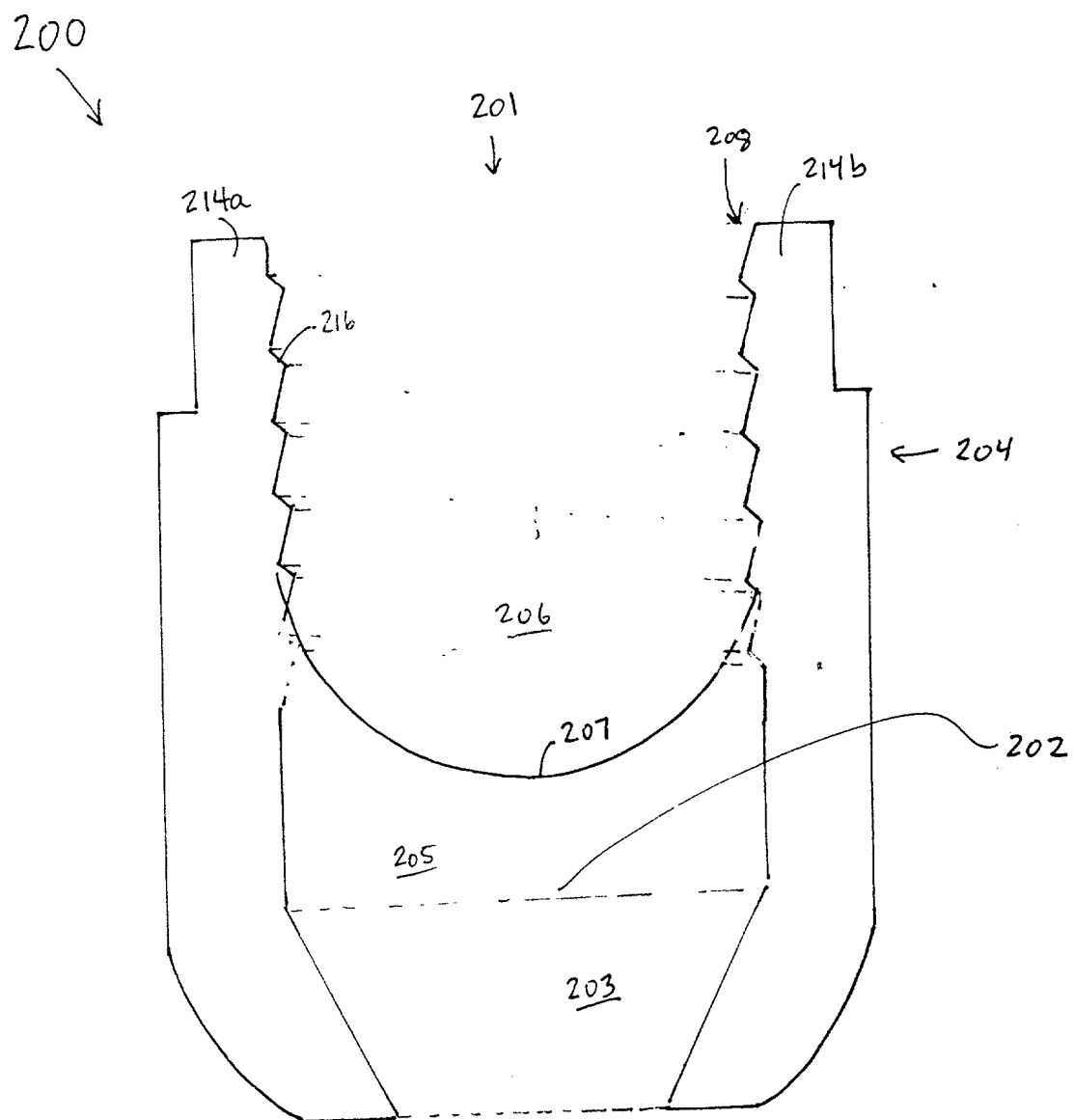


Fig. 7

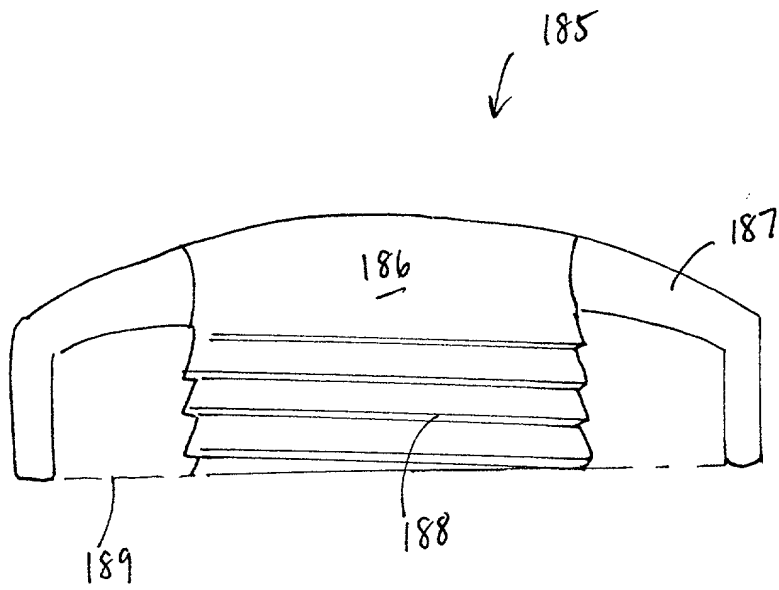


Fig. 8

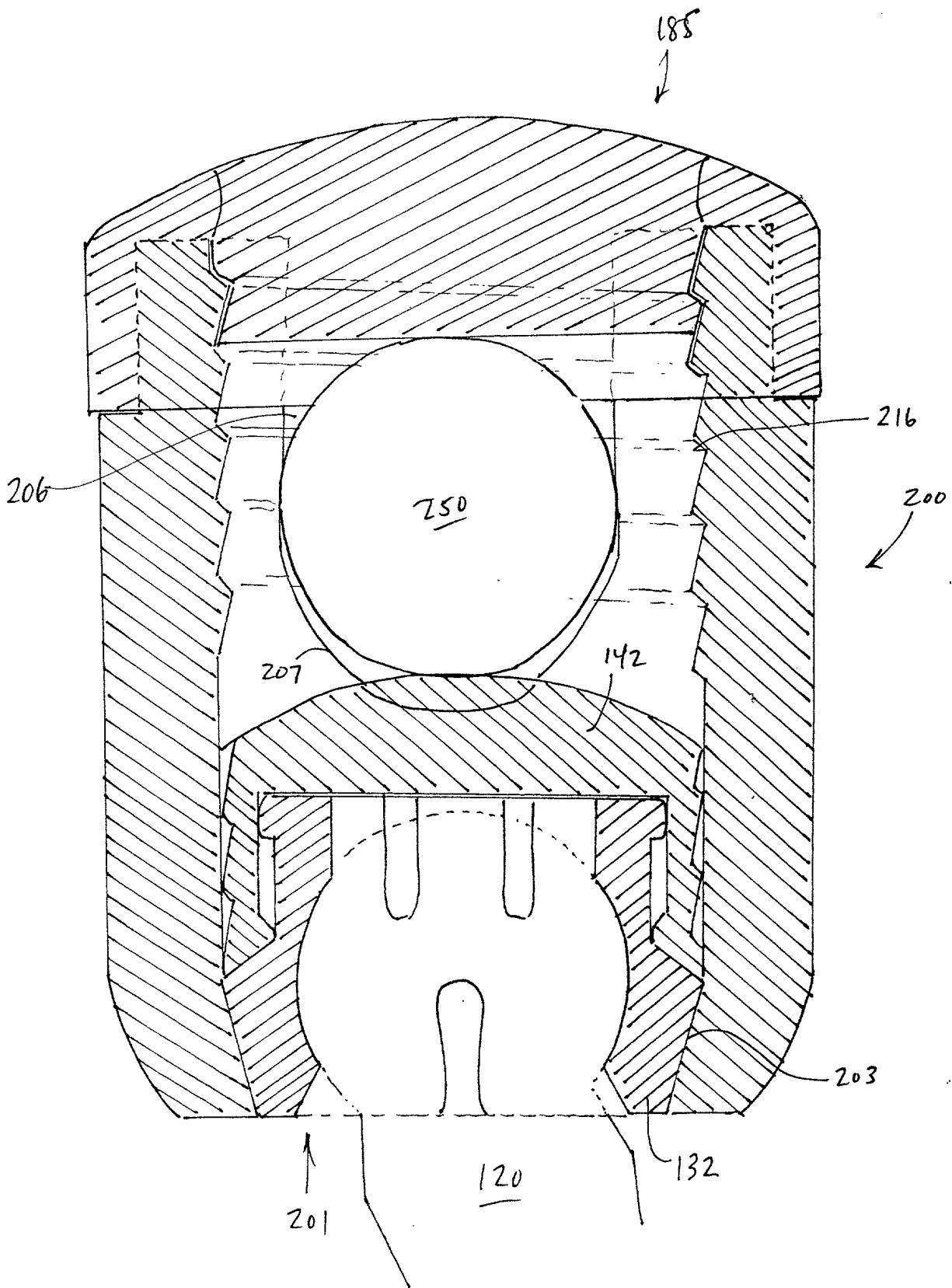


Fig 9

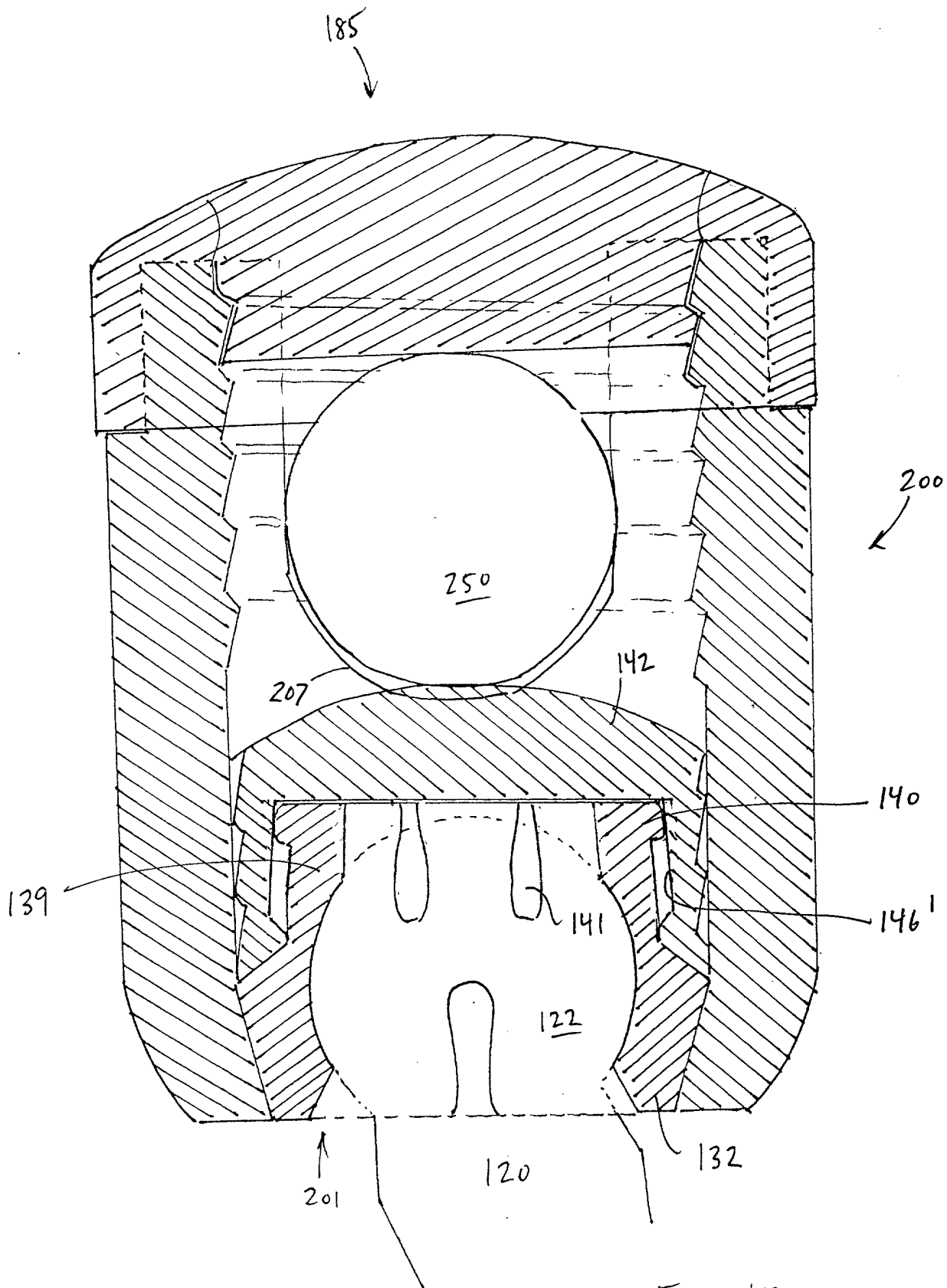


Fig 10

Docket No.

F-146A

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

A Polyaxial Pedicle Screw Having A Threaded And Tapered Compression Locking Mechanism

the specification of which (check one)

☒ is attached hereto.

☐ was filed on _____ as United States Application No. or PCT International Application Number

_____ and was amended on _____

(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Priority Not Claimed

(Number)

(Country)

Day/Month/Year Filed

☐

(Number)

(Country)

Day/Month/Year Filed

☐

(Number)

(Country)

Day/Month/Year Filed

☐

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Docket No.

F-146A

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

(Application Serial No.) (Filing Date)

(Application Serial No.) (Filing Date)

(Application Serial No.) (Filing Date)

I hereby claim the benefit under 35 U.S.C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112. I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C.F.R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

08/606,221 February 23, 1996 issued (5,607,426)
(Application Serial No.) (Filing Date) (patented, pending, abandoned)

08/843,972 April 17, 1997 pending
(Application Serial No.) (Filing Date) (patented, pending, abandoned)

(Application Serial No.) (Filing Date) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Docket No.

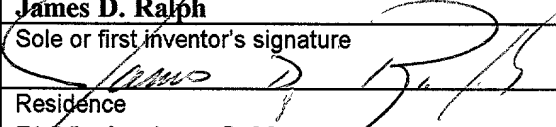
F-146A

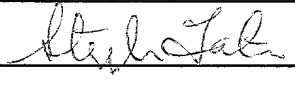
POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

Joseph P. Errico, Esq.
Reg. No. 38,131

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Sole or first inventor's signature 	Date 12-29-97
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Full name of second inventor, if any Stephen Tatar	
Second inventor's signature 	Date 12/29/97
Residence 45 Upper Mountain Ave., Montvale NJ 07045	
Citizenship USA	
Post Office Address same as above	

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) AND 1.27(c)) - SMALL BUSINESS CONCERNS			Docket No. F-146A
Serial No.	Filing Date January 2, 1998	Patent No.	Issue Date
Applicant/ Patentee: James D. Ralph and Steven Tatar			
Invention: A Polyaxial Pedicle Screw Having A Threaded And Tapered Compression Locking Mechanism			
<p>I hereby declare that I am:</p> <p><input type="checkbox"/> the owner of the small business concern identified below:</p> <p><input checked="" type="checkbox"/> an official of the small business concern empowered to act on behalf of the concern identified below:</p> <p>NAME OF CONCERN: Fastenetix, LLC</p> <p>ADDRESS OF CONCERN: 47 Maple Ave., Suite L-28, Summit, NJ 07901</p> <p>I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41 (a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.</p> <p>I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the above identified invention described in:</p> <p><input checked="" type="checkbox"/> the specification filed herewith with title as listed above.</p> <p><input type="checkbox"/> the application identified above.</p> <p><input type="checkbox"/> the patent identified above.</p> <p>If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed on the next page and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).</p>			
Patent and Trademark Office-U.S. DEPARTMENT OF COMMERCE			

Docket No.

F-146A

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☒ no such person, concern or organization exists.
☐ each such person, concern or organization is listed below.

FULL NAME

ADDRESS NAME

☐ Individual☐ Small Business Concern☐ Nonprofit Organization

FULL NAME

ADDRESS NAME

☐ Individual☐ Small Business Concern☐ Nonprofit Organization

FULL NAME

ADDRESS NAME

☐ Individual☐ Small Business Concern☐ Nonprofit Organization

FULL NAME

ADDRESS NAME

☐ Individual☐ Small Business Concern☐ Nonprofit Organization

Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING:

Thomas J. Errico

TITLE OF PERSON SIGNING

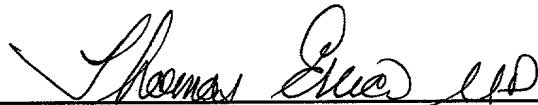
OTHER THAN OWNER:

President

ADDRESS OF PERSON SIGNING:

5 Crest Acre Ct.
Summit, NJ 07901

SIGNATURE:



DATE:

10/29/97